

Department of Health and Human Services

§ 61.13

and collected in the same manner as CMPs under subsection (a) of section 1128A of the Act. The Secretary will provide for publication of a public report that identifies those Government agencies that have failed to report information on other adjudicated actions as required to be reported under this section.

Subpart C—Disclosure of Information by the Healthcare Integrity and Protection Data Bank

§ 61.12 Requesting information from the Healthcare Integrity and Protection Data Bank.

(a) *Who may request information and what information may be available.* Information in the HIPDB will be available, upon request, to the following persons or entities, or their authorized agents—

(1) Federal and State Government agencies;

(2) Health plans;

(3) A health care practitioner, provider, or supplier requesting information concerning himself, herself or itself; and

(4) A person or entity requesting statistical information, which does not permit identification of any individual or entity. (For example, researchers can use statistical information to identify the total number of practitioners excluded from the Medicare and Medicaid programs. Similarly, health plans can use statistical information to develop outcome measures in their efforts to monitor and improve quality care.)

(b) *Procedures for obtaining HIPDB information.* Eligible individuals and entities may obtain information from the HIPDB by submitting a request in such form and manner as the Secretary may prescribe. These requests are subject to fees set forth in § 61.13. The HIPDB will comply with the Department's principles of fair information practice by providing each subject of a report with a copy when the report is entered into the HIPDB.

(c) *Information provided in response to self-queries.* (1) At the time subjects request information as part of a "self-query," the subject will receive—

(i) Any report(s) in the HIPDB specific to them; and

(ii) A disclosure history from the HIPDB of the name(s) of any entity (or entities) that have previously received the report(s).

(2) The disclosure history will be restricted in accordance with the Privacy Act regulations set forth in 45 CFR part 5b.

§ 61.13 Fees applicable to requests for information.

(a) *Policy on fees.* The fees described in this section apply to all requests for information from the HIPDB, except requests from Federal agencies. However, for purposes of verification and dispute resolution at the time the report is accepted, the HIPDB will provide a copy—at the time a report has been submitted automatically, without a request and free of charge—of every report to the health care provider, supplier or practitioner who is the subject of the report. For the same purpose, the Department will provide a copy of the report—at the time a report has been submitted automatically, without a request and free of charge—to the reporter that submitted it. The fees are authorized by section 1128E(d)(2) of the Act, and they reflect the full costs of operating the database. The actual fees will be announced by the Secretary in periodic notices in the FEDERAL REGISTER.

(b) *Criteria for determining the fee.* The amount of each fee will be determined based on the following criteria —

(1) Direct and indirect personnel costs;

(2) Physical overhead, consulting, and other indirect costs including rent and depreciation on land, buildings and equipment;

(3) Agency management and supervisory costs;

(4) Costs of enforcement, research and establishment of regulations and guidance;

(5) Use of electronic data processing equipment to collect and maintain information—the actual cost of the service, including computer search time, runs and printouts; and

(6) Any other direct or indirect costs related to the provision of services.

§ 61.14

(c) *Assessing and collecting fees.* The Secretary will announce through periodic notice in the FEDERAL REGISTER the method of payment of fees. In determining these methods, the Secretary will consider efficiency, effectiveness and convenience for users and for the Department. Methods may include credit card, electronic funds transfer and other methods of electronic payment.

§ 61.14 Confidentiality of Healthcare Integrity and Protection Data Bank information.

Information reported to the HIPDB is considered confidential and will not be disclosed outside the Department, except as specified in §§ 61.12 and 61.15. Persons and entities receiving information from the HIPDB, either directly or from another party, must use it solely with respect to the purpose for which it was provided. Nothing in this section will prevent the disclosure of information by a party from its own files used to create such reports where disclosure is otherwise authorized under applicable State or Federal law.

§ 61.15 How to dispute the accuracy of Healthcare Integrity and Protection Data Bank information.

(a) *Who may dispute the HIPDB information.* The HIPDB will routinely mail or transmit electronically to the subject a copy of the report filed in the HIPDB. In addition, as indicated in § 61.12(a)(3), the subject may also request a copy of such report. The subject of the report or a designated representative may dispute the accuracy of a report concerning himself, herself or itself as set forth in paragraph (b) of this section.

(b) *Procedures for disputing a report with the reporting entity.* If the subject disagrees with the reported information, the subject must request in writing that the HIPDB enter the report into “disputed status.”

(2) The HIPDB will send the report, with a notation that the report has been placed in “disputed status,” to queriers (where identifiable), the reporting entity and the subject of the report.

(3) The subject must attempt to enter into discussion with the reporting enti-

45 CFR Subtitle A (10–1–07 Edition)

ty to resolve the dispute. If the reporting entity revises the information originally submitted to the HIPDB, the HIPDB will notify the subject and all entities to whom reports have been sent that the original information has been revised. If the reporting entity does not revise the reported information, or does not respond to the subject within 60 days, the subject may request that the Secretary review the report for accuracy. The Secretary will decide whether to correct the report within 30 days of the request. This time frame may be extended for good cause. The subject also may provide a statement to the HIPDB, either directly or through a designated representative, that will permanently append the report.

(c) *Procedures for requesting a Secretarial review.* The subject must request, in writing, that the Secretary of the Department review the report for accuracy. The subject must return this request to the HIPDB along with appropriate materials that support the subject’s position. The Secretary will only review the accuracy of the reported information, and will not consider the merits or appropriateness of the action or the due process that the subject received.

(2) After the review, if the Secretary—

(i) Concludes that the information is accurate and reportable to the HIPDB, the Secretary will inform the subject and the HIPDB of the determination. The Secretary will include a brief statement (Secretarial Statement) in the report that describes the basis for the decision. The report will be removed from “disputed status.” The HIPDB will distribute the corrected report and statement(s) to previous queriers (where identifiable), the reporting entity and the subject of the report.

(ii) Concludes that the information contained in the report is inaccurate, the Secretary will inform the subject of the determination and direct the HIPDB or the reporting entity to revise the report. The Secretary will include a brief statement (Secretarial Statement) in the report describing the findings. The HIPDB will distribute the corrected report and statement (s) to